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15
 16 UNITED STATES DISTRICT COURT
 17 NORTHERN DISTRICT OF CALIFORNIA
 18 SAN FRANCISCO DIVISION

19
 20 In re GILEAD SCIENCES SECURITIES
 21 LITIGATION,

Master File No. C-03-4999-SI

CLASS ACTION

**DEFENDANTS' NOTICE OF MOTION AND
 MOTION TO DISMISS PLAINTIFFS' FIFTH
 CONSOLIDATED AMENDED CLASS
 ACTION COMPLAINT; MEMORANDUM OF
 POINTS AND AUTHORITIES IN SUPPORT
 THEREOF**

Date: October 9, 2009

Time: 9:00 a.m.

Dept: Courtroom 10

Judge: Honorable Susan Illston

Trial Date: None set

This Document Relates To:

ALL ACTIONS

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NOTICE OF MOTION AND MOTION TO DISMISS**TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD IN THIS MATTER:**

PLEASE TAKE NOTE that on October 9, 2009, at 9:00 a.m., or as soon thereafter as this motion may be heard, defendants Gilead Sciences, Inc. (“Gilead” or the “Company”), John C. Martin, John F. Milligan, Mark L. Perry, Norbert W. Bischofberger, Anthony Carraciolo, and William A. Lee (collectively “Defendants”) will and hereby do move to dismiss all claims asserted against them in Plaintiffs’ Fifth Consolidated Amended Class Action Complaint (“Fifth Amended Complaint”), pursuant to Federal Rules of Civil Procedure 8(a), 9(b), and 12(b)(6) and Section 21D(b) of the Securities Exchange Act of 1934 (“Exchange Act” or “PSLRA”) (15 U.S.C. § 78u-4(b)). Defendants seek an order dismissing Plaintiffs’ Fifth Amended Complaint without leave to amend. This motion is based on the papers on file; the accompanying Memorandum of Points and Authorities; Defendants’ Request for Judicial Notice (“RJN”); the Declaration of Matthew D. Brown; and such other matters as may be presented in connection with the hearing on the motion.

STATEMENT OF ISSUES TO BE DECIDED

1. With respect to the first claim for relief (violation of Exchange Act § 10(b)), whether Plaintiffs’ confidential witness allegations are reliable and adequately allege that there were significant sales resulting from off-label marketing during the class period.

2. With respect to the first claim for relief (violation of Exchange Act § 10(b)), whether Plaintiffs adequately plead that defendants Mark L. Perry, Norbert W. Bischofberger, Anthony Carraciolo, and William A. Lee made false and misleading statements.

3. With respect to the second claim for relief (violation of Exchange Act § 20(a)), whether Plaintiffs adequately plead that the individual defendants are liable as control persons.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Despite having had nearly six years to investigate their claims, and despite having filed six versions of the complaint, Plaintiffs still have failed to assert a single reliable allegation of significant sales of Viread during the class period that were the result of improper off-label marketing. There are still no allegations from any doctor stating that he or she prescribed Viread as a result of improper off-label marketing by Gilead during the class period. There are still no allegations of any internal reports at Gilead attributing sales during the class period to improper marketing. And there is still not a single allegation by a reliable confidential witness of significant Viread sales during the class period that were the result of off-label marketing. This Court dismissed the Fourth Amended Complaint for failing to cure this fundamental deficiency. The Court instructed Plaintiffs that there were two simple ways to fix this problem: (1) provide a credible explanation as to why confidential witness (“CW”) 2 changed his/her story, from saying in the Consolidated Amended Complaint that she/he “refused” to engage in off-label marketing to saying in the Fourth Amended Complaint that 85 to 90 percent of his/her sales resulted from off-label marketing; or (2) identify other reliable confidential witnesses who allege significant sales of Viread that were the result of off-label marketing during the class period. Plaintiffs have failed to do either, and, as a result, the Fifth Amended Complaint should be dismissed.

The explanation provided in the Fifth Amended Complaint for CW2’s changing story does nothing to restore reliability to those allegations. In fact, it further undercuts CW2’s reliability. Plaintiffs state for the first time that when CW2 asserted in the Consolidated Amended Complaint that he/she refused to market Viread off-label, this really meant he/she refused to increase the amount of off-label marketing he/she was doing even though purportedly 85 to 90 percent of his/her sales already resulted from his/her off-label marketing. This is plainly not an issue of “inartful drafting,” as Plaintiffs suggest; the two stories are fundamentally incompatible. Further, it is impossible to give credence to the notion that it was acceptable to CW2 for 90 percent of his/her sales to be attributable to off-label marketing, but that it somehow

1 would have been unacceptable to CW2 if, say, 91 percent or 92 percent of his/her sales were due
 2 to off-label marketing. The explanation lacks credibility.

3 The second possible fix was for Plaintiffs to find confidential witnesses who could allege
 4 that they sold a significant amount of Viread during the class period as a result of improper off-
 5 label marketing. Plaintiffs have failed to do so. Plaintiffs added six new confidential witnesses to
 6 the Fifth Amended Complaint, many of whom make allegations regarding pre-class period
 7 activities and training materials. One confidential witness was not even employed during the
 8 class period, and only two are specifically alleged to have been sales people during the class
 9 period. Of these two sales people, one does not allege that he/she sold Viread as a result of off-
 10 label marketing during the class period or at any other time. The other provides an allegation of
 11 off-label marketing and resulting sales but does not tie them to the class period. Glaringly absent
 12 from Plaintiffs' new allegations is a simple, declarative statement by any confidential witness
 13 alleging that he or she sold a significant amount of Viread during the class period as a result of
 14 improper marketing activities. Instead, Plaintiffs provide carefully crafted allegations that
 15 insinuate the possibility of, but stop short of actually alleging, off-label marketing and resulting
 16 sales during the class period.

17 The Court suggested two simple fixes, and Plaintiffs failed to deliver. Accordingly, the
 18 Fifth Amended Complaint should be dismissed with prejudice as to all Defendants.

19 The Fifth Amended Complaint must be dismissed on a separate and independent ground
 20 as to defendants Mark L. Perry, Norbert W. Bischofberger, Anthony Carraciolo, and William A.
 21 Lee because Plaintiffs fail to plead that any of these individuals made a false or misleading
 22 statement or that they substantially participated in the preparation of a false or misleading
 23 statement. Despite amending their complaint five times over almost six years, Plaintiffs do not
 24 present any specific allegations regarding Perry, Bischofberger, Carraciolo, and Lee's roles in the
 25 preparation of the alleged false press releases and SEC filings.

26 Finally, there are insufficient allegations to state a claim for "control person" liability.

27

28

1 **II. FACTUAL AND PROCEDURAL BACKGROUND**

2 **A. Events Giving Rise to Plaintiffs' Lawsuit**

3 The demand for Viread is created when doctors prescribe the drug for patients. (¶¶ 5, 9,
 4 236.¹) Like most drug manufacturers, Gilead does not typically sell directly to those patients or
 5 their doctors, but instead to pharmaceutical wholesalers, three of which purchase the vast majority
 6 of all Viread sold by Gilead. (¶¶ 224-25.) Gilead sets the price for Viread, and pharmaceutical
 7 wholesalers then supply pharmacies, who in turn fill prescriptions for the drug. (¶ 226.)
 8 Pharmaceutical wholesalers make much of their profit by buying large quantities of a drug before
 9 an expected manufacturers' price increase and later selling the drug at the new higher price. (*Id.*)
 10 In the second quarter of 2003, anticipating a price increase for Viread, Gilead's wholesalers
 11 bought excess quantities of the drug at the then-prevailing price, resulting in larger than normal
 12 wholesaler inventory levels by the end of the quarter. (¶ 229.) As a result of the inventory
 13 stocking and other factors, Gilead reported larger-than-forecasted revenues for the second quarter.

14 **1. Gilead's Second Quarter 2003 Earnings Releases**

15 In July 2003, Gilead announced that its second quarter revenues had increased, identifying
 16 three major causes: increasing prescription levels for Viread; a significant increase in wholesaler
 17 inventory levels of Viread; and a favorable foreign currency exchange rate. (¶¶ 232, 241.) Not
 18 knowing the precise amount that the inventory levels had increased at its major wholesalers
 19 during the quarter, Gilead *estimated* that the Viread "inventory build" accounted for \$25 to \$30
 20 million of second quarter Viread sales. (¶ 241.)

21 Specifically, on July 14, 2003, Gilead announced in a press release that its net second
 22 quarter revenues were projected to be well above analysts' estimates and stated:

23 Gilead expects that Viread sales will be approximately \$165 million for the
 24 quarter, compared to \$107 million for the first quarter of 2003. Increasing
 25 Viread sales reflect broader prescribing patterns in all commercial markets, as
 26 well as increases in U.S. wholesaler inventory levels in the second quarter in
 27 anticipation of a Viread price increase, which was implemented on June 27,
 28 2003.

¹ Citations in this format are to the Fifth Amended Complaint.

1 (¶ 232–33; Declaration of Matthew D. Brown in Support of Defendants' Motion to Dismiss
 2 Plaintiffs' Fifth Consolidated Amended Class Action Complaint ("Brown Decl."), Ex. A.)

3 Two weeks later, on July 31, 2003, Gilead issued a press release containing its final
 4 results for the second quarter. Gilead announced net quarterly revenues of \$238.9 million, of
 5 which \$167 million related to Viread. (¶ 241.) Gilead's press release explained that several
 6 factors had driven increased Viread sales:

7 Viread sales growth was primarily driven by higher prescription volume, a
 8 significant increase in U.S. wholesaler inventories and a favorable European
 9 currency environment compared to the same quarter last year. Gilead **estimates**
 that increased stocking by U.S. wholesalers accounted for \$25-30 million of
 Viread sales in the second quarter.

10 (¶ 241; Brown Decl., Ex. B (emphasis added).) The press release contained a warning regarding
 11 the forward-looking statements therein and warned of Gilead's limited "ability to accurately
 12 estimate inventory levels as we must make a great deal of assumptions and must rely on
 13 incomplete data to make these estimations . . ." (Brown Decl., Ex. B.)

14 **2. Gilead's Third Quarter Earnings Release**

15 On October 28, 2003, Gilead announced that, as anticipated, its third quarter Viread
 16 revenues had declined, but that both new and total prescriptions for the drug had increased.
 17 (¶ 262.) Gilead provided an updated estimate of \$33 to \$37 million for the size of the second
 18 quarter inventory build. (*Id.*) Specifically, Gilead stated:

19 Viread sales growth was primarily driven by higher prescription volumes in both
 20 the United States and Europe and a favorable European currency environment
 21 compared to the same quarter last year. After reviewing NDC prescription trends,
 22 IMS inventory data and actual Viread sales, Gilead estimates there was
 23 approximately \$33 to \$37 million of inventory reduction by U.S. pharmaceutical
 24 wholesalers during the third quarter of 2003 following an equivalent inventory
 build during the second quarter of 2003 . . . Although third quarter Viread
 25 revenues were down relative to the second quarter due to inventory de-stocking
 by U.S. wholesalers, important demand indicators, such as new and total
 26 prescriptions, showed continued growth during the quarter.

27 (Brown Decl., Ex. D (quotations omitted).)

28 Although Gilead's stock price fell \$7.46 (or 12.5 percent) to \$52.00 on October 29 from
 the closing price of \$59.46 the previous day, the price recovered nearly half that loss within one
 day and recovered fully within a month. (¶ 16; Brown Decl., Ex. E.)

1 **B. This Court's Order on Motion to Dismiss the Fourth Amended Complaint.**

2 On June 3, 2009, this Court granted in part and denied in part Defendants' motion to
 3 dismiss the Fourth Amended Complaint ("FAC"). (Docket No. 224 ("Order").) The Court
 4 explained that the earlier Consolidated Amended Complaint had been deficient, and therefore was
 5 dismissed, because there were insufficient allegations of sales resulting from improper off-label
 6 marketing that were material to the 2003 second quarter reports:

7 Judge Jenkins noted that "Plaintiffs have not alleged that any sales of Viread
 8 during the second quarter of 2003 were the result of improper off-label marketing
 9 activities," and that "even assuming Plaintiffs had alleged that such sales took
 place, Plaintiffs would also have to allege that those sales were 'material' to the
 second quarter reports."

10 (Order at 3:21–4:1 (quoting CAC Order, Docket No. 159, at 13).) The Court also explained that
 11 "[n]ot only did the FAC allege for the first time off-label sales of Viread during the second
 12 quarter of 2003, but also that such sales—attributable to CW2—were significant." (Order at 4:1-
 13 3.)

14 The Court then focused on whether Plaintiffs' two confidential witnesses were reliable
 15 under the standards enunciated in *Zucco Partners, LLC v. Digimarc Corporation*, 552 F.3d 981
 16 (9th Cir. 2009), and whether they sufficiently alleged significant sales during the class period
 17 resulting from off-label marketing. The Court held that because CW2's later allegations "flatly
 18 contradict[ed]" the earlier allegations in the CAC, the Court was "unable to find on this record
 19 that CW2's allegations about off-label sales during the class period are reliable." (Order at 4:14-
 20 15.) As to CW1, the Court held that because CW1 left Gilead before the class period, "any
 21 information CW1 has about sales during the class period is necessarily secondhand" and thus
 22 insufficient under *Zucco*. (Order at 5:4-7.) Accordingly, the Court dismissed the FAC because
 23 Plaintiffs failed to adequately allege that there were "significant off-label sales of Viread during
 24 the class period." (Order at 2 n.2.)

25 The Court, however, granted Plaintiffs leave to amend, stating:

26 [T]he Court GRANTS plaintiffs leave to amend to add further support to
 27 allegations of off-label sales during the class period. Plaintiffs may cure this
 28 deficiency by adding additional confidential witnesses who allege that there were
 off-label sales of Viread during the class period, and/or by providing an
 explanation of the change in CW2's allegations on this point.

1 (Order at 5:14-17.)

2 **C. The Fifth Amended Complaint**

3 In the Fifth Amended Complaint, Plaintiffs added allegations attributed to six new
 4 confidential witnesses, CW3 through CW8. Of these confidential witnesses, one was not
 5 employed by Gilead during the class period (CW4), and only two confidential witnesses are
 6 specifically alleged to have been Therapeutic Specialists (the term Gilead uses for its sales
 7 people) during the class period (CW6, CW8). (¶¶ 56, 67, 73.) The new allegations primarily
 8 relate to pre-class-period sales (¶¶ 51, 57, 97, 132) or to training materials that might have
 9 included off-label information (¶¶ 63, 91, 96, 129, 148, 153-58, 159-61, 166, 197). One
 10 confidential witness, CW7, alleges that a portion of his/her sales were to doctors who prescribed
 11 Viread off-label, but it is not clear that the doctors' prescriptions resulted from any off-label
 12 marketing. (¶ 72.) In any event, CW7 does not allege that these sales occurred during the class
 13 period and Plaintiffs do not allege that he/she was a Therapeutic Specialist during the class
 14 period. (¶ 72.) Another confidential witness, CW8, was allegedly a Therapeutic Specialist during
 15 the class period but does not allege that any of his/her sales were the result of off-label marketing.
 16 (See ¶¶ 73, 96, 108, 125.) The complaint alleges that roughly 70 percent of the sales of one
 17 confidential witness, CW6, were the result of off-label marketing and that he/she sold between
 18 \$400,000 to \$500,000 of Viread per month. (¶ 206.) However, Plaintiffs do not link any of those
 19 sales directly to the class period. In any event, during 2003, Gilead sold over \$566 million of
 20 Viread, or roughly \$47 million per month (Brown Decl., Ex. F at 39), so this one individual's
 21 sales likely averaged less than one percent of the Company's overall monthly sales.

22 **D. Defendants**

23 Defendant Gilead is a biopharmaceutical company, headquartered in Foster City,
 24 California, that discovers, develops, and commercializes therapeutics for the care of patients with
 25 life-threatening diseases. (¶ 22.) The individual defendants are:

- 26 o **John Martin**, Gilead's President and Chief Executive Officer (¶ 23).

27

28

- 1 ○ **John F. Milligan**, Gilead's Chief Financial Officer and Senior Vice-President (¶ 24). Mr.
2 Milligan is not alleged to have made any statement during the class period. He signed the
3 August 14, 2003 Form 10-Q (¶ 254; Brown Decl., Ex. C).
- 4 ○ **Mark L. Perry**, Gilead's Executive Vice-President, Operations (¶ 25). Perry is not alleged to
5 have made any statement during the class period. Further, there are no specific allegations as
6 to Perry's role in preparing any of the alleged false statements. The only specific allegations
7 as to Perry are that he attended some meetings (primarily pre-class period) where allegedly
8 off-label materials were provided to sales people (*see, e.g.*, ¶¶ 85, 87, 136, 143) and that he
9 sold stock during the class period (¶ 274).
- 10 ○ **Norbert W. Bischofberger**, Gilead's Executive Vice-President, Research and Development
11 (¶ 26). Bischofberger is not alleged to have made any statement during the class period.
12 Further, there are no specific allegations as to Bischofberger's role in preparing any of the
13 alleged false statements. Similar to Perry, the only specific allegations as to Bischofberger
14 are that he attended some meetings (primarily pre-class period) where allegedly off-label
15 materials were provided to sales people (*see e.g.* ¶¶ 85, 87, 143), that he made presentations to
16 the sales staff (¶ 152), and that he sold stock during the class period (¶ 274).
- 17 ○ **Anthony Carraciolo**, Gilead's Vice-President (¶ 27). Carraciolo is not alleged to have made
18 any statement during the class period. Further, there are no specific allegations as to
19 Carraciolo's role in preparing any of the alleged false statements. The only specific allegation
20 as to Carraciolo is that he sold stock during the class period. (¶ 274).
- 21 ○ **William A. Lee**, Gilead's Senior Vice-President, Research (¶ 28). Lee is not alleged to have
22 made any statement during the class period. Further, there are no specific allegations as to
23 Lee's role in preparing any of the alleged false statements. As with Perry and Bischofberger,
24 there are only a few specific allegations as to Lee in the entire complaint and they relate
25 primarily to his alleged attendance at a few meetings (primarily pre-class period) where
26 allegedly off-label materials were provided to sales people (*see, e.g.*, ¶¶ 85, 165) and that he
27 sold stock during the class period (¶ 274).

28

1 **III. LEGAL STANDARDS**

2 Pursuant to Federal Rule of Civil Procedure 12(b)(6), courts may dismiss a complaint as a
 3 matter of law for two reasons: (1) lack of a cognizable legal theory; or (2) insufficient facts under
 4 a cognizable legal theory. *Robertson v. Dean Witter Reynolds, Inc.*, 749 F.2d 530, 534 (9th Cir.
 5 1984). In deciding a motion to dismiss, the court must accept all well-pleaded factual allegations
 6 as true. *See Blake v. Dierdorff*, 856 F.2d 1365, 1368 (9th Cir. 1988). The court need not,
 7 however, accept legal conclusions asserted as “facts.” *In re VeriFone Sec. Litig.*, 784 F. Supp.
 8 1471, 1476 n.5 (N.D. Cal. 1992) (citation omitted), *aff’d*, 11 F.3d 865 (9th Cir. 1993). Further,
 9 judicial notice of documents that plaintiffs reference in their complaint is appropriate under the
 10 doctrine of incorporation by reference and other theories. *Branch v. Tunnell*, 14 F.3d 449, 454
 11 (9th Cir. 1994), *overruled on other grounds by Galbraith v. County of Santa Clara*, 307 F.3d
 12 1119 (9th Cir. 2002).

13 To state a claim under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated
 14 thereunder, plaintiffs must allege: (1) a misstatement or omission (2) of material fact (3) made
 15 with scienter (4) on which they relied (5) which proximately caused plaintiffs’ injury. *DSAM*
Global Value Fund v. Altris Software, Inc., 288 F.3d 385, 388 (9th Cir. 2002) (citation omitted).
 16 There is no secondary liability under section 10(b) for aiding and abetting, and, similarly, there is
 17 no scheme liability under section 10(b). *See Central Bank of Denver, N.A. v. First Interstate*
Bank of Denver, 511 U.S. 164, 177 (1994); *Stoneridge Inv. Partners v. Scientific-Atlanta, Inc.*,
 18 128 S. Ct. 761, 770 (2008). Each individual defendant must be a primary violator of section
 19 10(b). In order to state a claim for primary liability under section 10(b) against an individual
 20 defendant, a plaintiff must allege either that the defendant personally made a public statement or
 21 omission that was misleading to investors or that the defendant personally committed a
 22 manipulative act that deceived investors. *Central Bank*, 511 U.S. at 177.

23 Federal Rule of Civil Procedure 9(b) requires that plaintiffs “state with particularity the
 24 circumstances constituting fraud or mistake.” Rule 9(b) “requires the inclusion of specific facts
 25 regarding the alleged fraudulent activity, such as the time, date, places, content of each fraudulent
 26 representation, the reasons that the representation is false, and the identity of the person or

1 persons engaged in the fraud.” *In re Autodesk, Inc. Sec. Litig.*, 132 F. Supp. 2d 833, 839 (N.D.
 2 Cal. 2000) (citation omitted). Further, the PSLRA significantly heightens pleading requirements
 3 in private securities litigation in order to eliminate meritless claims and imposes even more
 4 stringent requirements for pleading falsity and scienter. *In re Silicon Graphics, Inc. Sec. Litig.*,
 5 183 F.3d 970, 988 (9th Cir. 1999). Specifically, both falsity and scienter must be pleaded with
 6 particularity. 15 U.S.C. § 78u-4(b)(1)-(3).

7 **IV. ARGUMENT**

8 **A. The Fifth Amended Complaint Should Be Dismissed as to All Defendants
 9 Because It Does Not Adequately Allege Significant Sales of Viread Resulting
 From Improper Off-Label Marketing During the Class Period.**

10 This Court dismissed the Fourth Amended Complaint for the same reason that Judge
 11 Jenkins had previously found the prior complaints lacking: Plaintiffs failed to adequately allege
 12 that there were significant class period sales attributable to improper off-label marketing. (Order
 13 at 3:21–4:1.) Plaintiffs had relied on two confidential witnesses, CW1 and CW2, each of whom
 14 the Court found to be unreliable (albeit for different reasons) on the issue of class period sales. In
 15 the Fifth Amended Complaint, Plaintiffs continue to rely solely on confidential witnesses on this
 16 point, adding allegations attributed to six new confidential witnesses. When the new allegations
 17 are reviewed carefully, it becomes clear that, as before, the complaint does not adequately allege
 18 significant sales during the class period that were caused by off-label marketing.

19 **1. The allegations attributed to CW1 have not changed and thus remain
 20 inadequate as to sales during the class period that were the result of
 off-label marketing.**

21 In its Order on the Fourth Amended Complaint, this Court held that, because CW1 left
 22 Gilead before the class period, “any information CW1 has about sales during the class period is
 23 necessarily secondhand” and thus insufficient under *Zucco*. (Order at 5:4-7.) Plaintiffs have not
 24 added any new allegations attributable to or regarding CW1. Further, nothing could change the
 25 fact that CW1 left Gilead before the class period and, thus, does not have personal knowledge of
 26 sales during that time resulting from off-label marketing.

27

28

1 2. **The purported explanation for CW2's change of story from one
2 pleading to another is unpersuasive and thus there are no reliable
3 allegations of sales during the class period as a result of off-label
4 marketing.**

5 The Court previously held that CW2 was unreliable because he/she changed his/her story
6 concerning whether or not he/she engaged in off-label marketing during the class period. (Order
7 at 4:14-15.) The Court instructed Plaintiffs that, to rehabilitate CW2, they needed to provide an
8 explanation as to why his/her story changed. Plaintiffs' explanation is unpersuasive.

9 As the Court may recall, in the Consolidated Amended Complaint (Docket No. 50
10 ("CAC")) filed in April 2004, Plaintiffs alleged that CW2 *refused* to engage in off-label
11 marketing and left the company rather than do so:

12 ... Gilead executives provided CW2 with detailed off-label information for Viread
13 and told CW2, both overtly and covertly, to use that information to aggressively
14 promote and sell Viread . . . [¶] Nevertheless, despite his or her superiors'
15 pressure to market Viread utilizing off-label materials, CW2 refused. Ultimately
16 CW2 terminated his or her employment with Gilead rather than follow these
17 questionable directives to use off-label materials.

18 (CAC ¶¶ 49-50.)

19 In the Fourth Amended Complaint (Docket No. 139) filed in December 2005, the
20 allegations attributed to CW2 directly contradicted those in the Consolidated Amended
21 Complaint. Plaintiffs alleged that CW2 *did* engage in improper off-label marketing (FAC ¶¶ 48-
22 49) and that the overwhelming majority of CW2's sales were the result of those efforts:

23 Prior to Viread's inclusion in the Georgia ADAP formulary, CW2 sold
24 approximately between \$10 million and \$15 million of Viread. Of those sales,
25 CW2 estimates that 85%-90% were a result of off-label marketing. After
26 inclusion of the Georgia ADAP formulary (late 2002 through early 2004), CW2
27 sold approximately between \$15 million and \$20 million of Viread. Again, CW2
28 states that 85%-90% of those sales were caused by off-label marketing.

29 (FAC ¶ 148.)

30 Though the allegations attributed to CW2 in the Fourth Amended Complaint are carried
31 over in the Fifth Amended Complaint (¶¶ 47-48, 142, 204), Plaintiffs now attempt to explain this
32 change in CW2's story:

33 [W]hen CW2 stated that she/he refused to bow to "ever increasing pressure" to
34 market Viread using off-label information, CW2 did not mean she/he never used

1 off-label information, but that she/he refused to increase her/his use of off-label
 2 information to sell Viread. Viewed in this light, allegations attributed to CW2 in
 3 the CAC and the Fourth Amended Consolidated Complaint (“FAC”) are not
 4 contradictory. If anything, the original allegations in the CAC were inartfully
 5 drafted.

6 (Fifth Amended Complaint at 13, n.1.)

7 Plaintiffs’ explanation is unconvincing; the fundamental contradiction in the allegations
 8 attributed to CW2 cannot be explained away as mere inartful drafting. It is inexplicable how
 9 CW2 could claim that 90 percent of his/her sales were the result of off-label marketing and
 10 simultaneously claim that he/she left Gilead rather than succumb to pressure to increase his/her
 11 off-label marketing sales. This somehow supposes that for CW2, having 90 percent of his/her
 12 sales result from his/her off-label marketing activities would be acceptable, but having that figure
 13 rise to, say, 91 percent or 92 percent would become unacceptable. It is simply not plausible. This
 14 explanation only underscores that CW2 was either lying then or is lying now. In either event, he
 15 or she is not reliable. *See Zucco*, 552 F.3d at 995. Further, that Plaintiffs would put forth such a
 16 fanciful explanation and still assert allegations by such an unreliable witness undermines the
 17 reliability of Plaintiffs’ other confidential witness allegations.

18 **3. The new confidential witnesses, CW3 through CW8, do not adequately
 19 allege sales during the class period resulting from off-label marketing.**

20 Despite the six new confidential witnesses and many paragraphs of new allegations,
 21 Plaintiffs are still unable to adequately allege from a reliable confidential witness that there were
 22 significant off-label marketing sales that occurred during the class period as a result of improper
 23 off-label marketing. The Ninth Circuit has held that, if plaintiffs are relying on confidential
 24 witnesses, then those witnesses “must be described with sufficient particularity to establish their
 25 reliability and personal knowledge” of the facts they allege. *Zucco*, 552 F.3d at 995. Further, in
 26 evaluating the confidential witnesses, a court must consider “the level of detail provided by the
 27 confidential sources, the corroborative nature of the other facts alleged (including from other
 28 sources), the coherence and plausibility of the allegations, the number of sources, the reliability of
 29 the sources and similar indicia.” *Id.* (citation omitted). In the Fifth Amended Complaint,
 30 Plaintiffs’ confidential witness allegations are replete with conclusory statements, hearsay and

1 allegations that are vague as to time, and are often internally inconsistent. Particularly under the
 2 heightened scrutiny that *Zucco* requires of confidential witness allegations, there is no basis for
 3 concluding that there were significant off-label marketing sales during the class period.

4 **a. CW3 was not a sales person during the class period and has no**
 5 **personal knowledge of sales during the class period that were**
the result of off-label marketing.

6 CW3 has no personal knowledge of sales during the class period that were the result of
 7 off-label marketing, and his/her allegations are conclusory and inconsistent. CW3 purportedly
 8 worked for Gilead from 2000 until January 2005. However, he/she stopped working as a
 9 Therapeutic Specialist (sales person) in 2002, when he/she became a Training Manager. (¶¶ 49-
 10 55.) Thus, CW3 was not involved in selling Viread during the class period. As a result, any off-
 11 label marketing sales he/she might have made pre-class-period do not demonstrate that there were
 12 significant off-label marketing sales during the class period. Like the allegations attributed to
 13 CW1, CW3's allegations of off-label marketing sales during the class period are speculative.
 14 (Order at 4:18-19.)

15 Plaintiffs also allege that CW3 represented that a "large portion" of Gilead's sales during
 16 the class period were the result of off-label marketing. (¶¶ 52, 96.) This is nothing more than a
 17 conclusory allegation. Plaintiffs provide no basis for the Court to determine that CW3 was in a
 18 position to have personal knowledge of the portion of Gilead's sales that were the result of
 19 specific marketing techniques. CW3 does not allege that he/she personally made any class-period
 20 sales resulting from off-label marketing. Nor does CW3 allege that he/she attended any sales
 21 visits with Therapeutic Specialists where he/she witnessed sales as a result of improper off-label
 22 marketing. There is simply no basis to conclude that he/she had personal knowledge of any sales
 23 resulting from off-label marketing during the class period.

24 At most, CW3 has personal knowledge of the training materials he/she prepared for the
 25 sales people (¶¶ 148, 197), that he/she put watermarks on the materials stating they were for "not
 26 for promotional use" (¶ 157), and that there were discussions concerning what materials to give to
 27 the sales force (¶¶ 153-56). Noticeably, CW3 cannot even allege that he/she has personal
 28 knowledge of the materials that were presented to the sales force. CW3 concedes that he/she did

1 not actually present to the sales force any of the scripts or research he/she prepared; rather,
 2 according to CW3, that task would fall to the “Clinical Science” staff. (¶ 152.) Accordingly,
 3 CW3 does not even have personal knowledge regarding what was provided to the sales force.

4 Finally, CW3 alleges that 60 percent of HIV patients were “experienced,” 30 percent
 5 “naïve,” and 10 percent “salvage.” (¶ 169.)² This claim is in direct conflict with the allegation
 6 attributed to CW1 that off-label marketing was necessary because Viread was not approved for
 7 the majority of the HIV population (there is no dispute between the parties that Viread was
 8 approved for experienced HIV patients). (¶ 199.) This inconsistency, which bears directly on
 9 alleged motivations for off-label marketing, undermines the reliability of CW3 as well as CW1.

10 **b. CW4 was not employed at Gilead during the class period and
 11 has no personal knowledge of sales during the class period that
 were the result of off-label marketing.**

12 CW4 allegedly started at Gilead as a Medical Sciences Liaison in 1999 and was asked to
 13 leave the Company in January 2003. (¶ 56.) Thus, CW4 was not employed at Gilead during the
 14 class period, and does not and cannot allege anything regarding whether there were off-label
 15 marketing sales during the class period. *See Zucco*, 552 F.3d at 996 (holding that CW4 and CW5
 16 did not have personal knowledge because they were not employed during the class period);
 17 *Shurkin v. Golden State Vintners Inc.*, 471 F. Supp. 2d 998, 1015 (N.D. Cal. 2006) (“CW3’s
 18 employment ended before the Class Period and thus, CW3 lacks personal knowledge” as to
 19 activities during the class period); *Brodsky v. Yahoo! Inc.*, 592 F. Supp. 2d 1192, 1202 (N.D. Cal.
 20 2008) (refusing to rely on statements by confidential witness not employed by defendant during
 21 the class period). As with CW1, this makes any allegations attributed to CW4 regarding off-label
 22 marketing sales during the class period purely speculative. (*See* Order at 4:18-19.)

23 **c. CW5 was not a sales person during the class period and has no
 24 personal knowledge of sales during the class period that were
 the result of off-label marketing.**

25 CW5 allegedly worked for Gilead from 2001 through 2005 and is a former Therapeutic
 26 Specialist and Training Manager. (¶ 60.) According to the Fifth Amended Complaint, he/she

27 ² By contrast, CW1 allegedly claims that 50 to 60 percent of HIV patients fall in the treatment
 28 naïve category. (¶ 198.)

1 was promoted to Training Manager in late 2002 and ceased his/her sales activities. (*Id.*) As a
 2 result, CW5 does not and cannot allege that he/she made any sales as a result of off-label
 3 marketing during the class period, as he/she was not a sales person then. Further, CW5 does not
 4 even allege that he/she witnessed anyone making off-label marketing sales during the class
 5 period. CW5 alleges that training materials taught sales people about the off-label uses for
 6 Viread and also alleges that sales people could get around the “not-for-promotional use”
 7 watermark. (See e.g. ¶¶ 65, 159, 160, 161.) This does not amount to an allegation that there were
 8 significant sales resulting from improper marketing activities during the class period. Moreover,
 9 it is perfectly legal and understandable that Gilead would want its sales representatives fully
 10 informed about Viread, whether or not they could use the materials to promote it.

11 The closest CW5 comes to an allegation that is relevant to the deficiency identified by this
 12 Court is the allegation that Gilead marketed Viread using off-label materials to Dr. Cazen, a
 13 gastroenterologist in San Francisco, CA, who treated patients co-infected with HIV and Hepatitis
 14 B. (¶ 166.) However, Plaintiffs provide no basis for determining whether CW5 had personal
 15 knowledge of how Viread was marketed to Dr. Cazen during the class period or whether CW5 is
 16 just reporting rumor or hearsay.³ *Zucco*, 552 F.3d at 997 (holding confidential witness allegations
 17 based on hearsay insufficient to meet reliability standard); *In re Metawave Commc'n Corp. Sec.*
 18 *Litig.*, 298 F. Supp. 2d 1056, 1068 (W.D. Wash. 2003) (citation omitted). (“[T]he Court must be
 19 able to tell whether a confidential witness is speaking from personal knowledge or ‘merely
 20 regurgitating gossip and innuendo’ . . .”). Accordingly, Plaintiffs have not adequately pleaded
 21 sufficient facts to determine that CW5’s allegations are reliable. Moreover, even if reliable, these
 22 allegations do not support the contention that there were significant sales as a result of off-label
 23 marketing during the class period.

24
 25
 26 ³ Plaintiffs’ carefully crafted allegation in this regard says, in total: “CW5 recalled that Dr. Cazen
 27 was one particular gastroenterologist in the San Francisco, California area who treated co-infected
 28 patients and to whom Gilead marketed Viread as a treatment for Hepatitis B during the Class
 Period.” (¶ 166.)

d. CW6's allegations are insufficient to demonstrate that there were significant sales during the class period that were the result of off-label marketing.

Plaintiffs allege that CW6 worked as a Therapeutic Specialist at Gilead from March 2003 until January 2006. According to the complaint, CW6 marketed HIV pharmaceuticals to hospitals, clinics, and physicians in the Brooklyn and Queens area. (¶¶ 67-71.) Plaintiffs claim that CW6 alleged that he/she sold roughly \$400,000 to \$500,000 of Viread per month and that roughly 70 percent of the sales were to treatment naïve patients. (¶ 206.) Noticeably, nowhere do Plaintiffs specifically state that CW6 made sales of Viread as a result of off-label marketing *during the class period*. Rather, the allegations attributed to CW6—like the allegations attributed to the other confidential witnesses—appear carefully created to give the sense of expansive allegations while failing to actually state that any sales from off-label marketing occurred during the class period. This Court’s directive to Plaintiffs was simple and clear: add “confidential witnesses who allege that there were off-label marketing sales of Viread during the class period.” (Order at 5:16.) CW6 does not satisfy that directive.

Moreover, even if the Court were to consider Plaintiffs' artful allegations as sufficient to
allege some sales of Viread using off-label materials during the class period, this by itself falls
short of alleging that there were *significant* off-label marketing sales during the class period. By
CW6's own admission, he/she at most made \$280,000 to \$350,000 in off-label sales per month.
(¶ 206.) During 2003, Gilead sold over \$566 million of Viread, or roughly \$47 million per
month. (Brown Decl., Ex. F at 39.) Thus, CW6's alleged sales likely averaged less than one
percent of Gilead's overall monthly sales. Hence, there is no basis for extrapolating from such a
small sample and concluding that there were significant sales from improper marketing activities
during the class period. *See In re Zumiez Inc. Sec. Litig.*, No. C07-1980-JCC, 2009 WL 901934,
at *9 (W.D. Wash. Mar. 30, 2009) (holding that allegations by a dozen store managers that their
stores were underperforming were insufficient to support an inference of company-wide
problems).

27 Further, as will be shown below, CW7 and CW8's allegations undermine the reliability of
28 CW6's allegations.

e. CW7's allegations do not support an inference that there were significant sales during the class period that were the result of off-label marketing.

The complaint alleges that CW7 was a Therapeutic Specialist and Trainer for Gilead in Dallas, TX, who worked for Gilead from prior to 2002 until 2006. (¶ 72.) According to Plaintiffs, “CW7 estimated that, with regard to Hepatitis-B infected patients, 10% of her/his total Viread sales were off-label to treating physicians.” (¶ 72; *see also* ¶ 212 (“CW7 . . . stated that 10% of her/his total Viread sales were to Hepatitis B infected patients.”).) In addition, the complaint states that “CW7 believes the Company also was promoting Viread off-label in the pediatric population. CW7 estimates that her/his sales to a pediatric population were about 10% of her/his total sales.” (¶ 72.)

These allegations fail to demonstrate that there were significant sales resulting from off-label marketing during the class period. First, these curiously worded allegations do not directly state that CW7 actually engaged in off-label marketing of Viread or that CW7 has any firsthand knowledge of specific sales resulting from off-label marketing. To allege that 10 percent of CW7's total sales were to physicians prescribing the drug to patients with Hepatitis B and another 10 percent of his/her sales were to physicians prescribing the drug to pediatric patients is far different from saying that CW7 personally engaged in off-label marketing to physicians and that 20 percent of his/her total sales were the result of such off-label marketing. That CW7 "believes" that "the Company" was promoting Viread for off-label uses in the pediatric population does not give CW7 sufficient firsthand knowledge of actual sales that resulted from off-label marketing. And the mere fact that physicians were prescribing the drug for off-label uses is irrelevant. It is not illegal for doctors to prescribe drugs off-label, and, in fact, even in the absence of off-label marketing, off-label use is "commonplace in modern medical practice and ubiquitous in certain specialties." *Washington Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000); see also *In re Nuvelo Inc. Sec. Litig.*, No. C 07-4056 VRW, 2008 WL 5114325, at *15 (N.D. Cal. Dec. 4, 2008) (recognizing that the market understands that drugs are used off-label). Even the FDA acknowledges that, in some areas of medical practice, practitioners consider off-label use to

1 constitute the standard of good medical care. *See Washington Legal Found. v. Friedman*, 13 F.
 2 Supp. 2d 51, 56 (D.D.C. 1998), *vacated on other grounds by Henney*, 202 F.3d 331.

3 Second, the allegations are vague as to time. Plaintiffs fail to allege the dates on which
 4 CW7 was a Therapeutic Specialist (sales person), as opposed to the dates on which he/she was a
 5 Trainer. Therefore, even if the Court were to interpret the allegations as CW7 stating that he/she
 6 marketed Viread for off-label uses and that some portion of his/her sales were the result of such
 7 off-label marketing, Plaintiffs nevertheless have failed to tie any such sales to the class period.

8 **f. CW8's allegations do not support an inference that there were
 9 significant sales during the class period that were the result of
 off-label marketing.**

10 The complaint alleges that CW8 was a Therapeutic Specialist from April 2003 through
 11 mid-2008. (¶ 73.) Although CW8 allegedly was a sales person during the class period, CW8
 12 *does not* allege that he/she made any Viread sales during the class period as a result of off-label
 13 marketing. The failure of CW8 to allege *any* such sales during the class period undermines the
 14 contention that there were significant sales during the class period that were caused by off-label
 15 marketing.

16 Moreover, Plaintiffs have failed to provide sufficient detail about CW8's position to
 17 establish that CW8 was in a position to have personal knowledge of the facts he/she alleged. *See*
 18 *Zucco*, 552 F.3d at 995; *In re Daou Sys., Inc. Sec. Litig.*, 411 F.3d 1006, 1015-16 (9th Cir. 2005).
 19 Plaintiffs have only provided CW8's title and dates of employment. Plaintiffs do not provide any
 20 specifics regarding CW8's job responsibilities, the region in which he/she worked, or to whom
 21 he/she reported. Such a vague description is unacceptable under the PSLRA. *See Zucco*, 552
 22 F.3d at 996; *Daou*, 411 F.3d at 1016 (requiring, among other things, a description of
 23 responsibilities and an allegation of to whom the confidential witness reported).

24 * * * *

25 Quantity does not equal quality. Despite eight confidential witnesses and a ninety-page
 26 complaint spanning close to 300 paragraphs, there is not a single reliable allegation of significant
 27 sales of Viread as a result of off-label marketing during the class period. In dismissing the Fourth
 28 Amended Complaint, the Court gave Plaintiffs a simple task: find reliable confidential witnesses

1 who could allege that they made significant sales of Viread as a result of off-label marketing
 2 during the class period. Plaintiffs have failed to do so.

3 **B. The Fifth Amended Complaint Should Be Dismissed as to Defendants Perry,
 Bischofberger, Carraciolo, and Lee Because They Are Not Primary Violators
 of Section 10(b).**

5 There is no secondary liability under section 10(b) for aiding and abetting and, similarly,
 6 there is no scheme liability under section 10(b). *See Central Bank*, 511 U.S. at 177; *Stoneridge*,
 7 128 S. Ct. at 770. To be liable under section 10(b), an individual must be a primary violator of
 8 the statute. *Central Bank*, 511 U.S. at 177. In order to state a claim for primary liability under
 9 section 10(b), plaintiffs must allege either that the defendant made a public statement or omission
 10 that was misleading to investors or that the defendant personally committed a manipulative act
 11 that deceived investors.⁴ *Central Bank*, 511 U.S. at 177; *see also Stoneridge*, 128 S. Ct. at 769.
 12 Conduct that only assists another in making a misleading public statement or in engaging in a
 13 manipulative act is not actionable under section 10(b). *See Central Bank*, 511 U.S. at 177. The
 14 Ninth Circuit has interpreted this to mean that an individual must either make a statement or have
 15 “substantial participation or intricate involvement in the preparation of fraudulent statements.”
 16 *Howard v. Everex Sys., Inc.*, 228 F.3d 1057, 1061 n.5 (9th Cir. 2000).

17 **1. Plaintiffs fail to adequately allege that Defendants Perry,
 Bischofberger, Carraciolo, and Lee made any false statements or
 substantially participated in the preparation of any false statements.**

19 Defendants Perry, Bischofberger, Carraciolo, and Lee (the “Non-Speaking Defendants”)
 20 did not make any statements and did not even sign any statements. (*See ¶¶ 232, 237, 241, 255.*)
 21 Moreover, despite the length of the Fifth Amended Complaint, there are no specific allegations
 22 regarding the involvement or participation, if any, in preparing Gilead’s financial statements or
 23
 24

25 ⁴ “Manipulative acts” typically include fraudulent devices that are unconnected to public
 26 statements, but nonetheless deceive the market or an investor. *See Santa Fe Indus. Inc. v. Green*,
 27 430 U.S. 462, 476-77 (1977) (*citing Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 199 (1976))
 28 (“[m]anipulation’ is virtually a term of art when used in connection with the securities markets”
 and “refers generally to practices, such as wash sales, matched orders, or rigged prices, that are
 intended to mislead investors by artificially affecting market activity”).

1 press releases of the Non-Speaking Defendants. Therefore, under established law, the Court must
 2 dismiss these individuals.⁵

3 For example, in *In re Cylink Securities Litigation*, 178 F. Supp. 2d 1077, 1084-85 (N.D.
 4 Cal. 2001), the district court dismissed claims against the Vice President of Sales and Marketing
 5 because he was not alleged to have made any of the public statements challenged as false, nor
 6 was he alleged to have been involved in the preparation of the challenged statements. The *Cylink*
 7 plaintiffs alleged that the Vice President “instructed the Cylink sales force to solicit” the
 8 transaction for which revenue was improperly recognized. *Id.* However, this was insufficient to
 9 hold the Vice President liable for the later incorrect financial statements because plaintiffs failed
 10 to allege that he was involved in the preparation of the alleged misleading statements. *Id.*
 11 Similarly, in *New York City Employees’ Retirement System v. Berry*, 616 F. Supp. 2d 987 (N.D.
 12 Cal. 2009), the court dismissed claims regarding statements that the company’s general counsel
 13 did not draft or sign because plaintiffs failed to specify her involvement in the preparation of
 14 those statements. Plaintiffs in *Berry* alleged that the defendant “was ‘substantially involved’ in
 15 the preparation of many of the documents that contained material misrepresentations, which were
 16 publicly disclosed by Juniper.” *Id.* at 994. The court, however, held that “such an allegation is,
 17 by itself, insufficient to state a claim of substantial participation” because it is merely a “legal
 18 conclusion couched in the form of a factual allegation.” *Id.* at 994–95.

19 In this case, Plaintiffs have provided no specific allegations regarding Perry,
 20 Bischofberger, Carraciolo, or Lee’s participation in the preparation of the alleged false statements.
 21 Like *Berry*, Plaintiffs here only make a legal conclusion—couched as a factual allegation—that
 22 all the defendants participated in the preparation of the financial statements. (¶ 29.) Thus, as in
 23

24 ⁵ This Court’s Order on the FAC included the following ruling pertaining to the individual
 25 defendants: “Finally, the Court finds that the FAC adequately pleads a basis for holding the
 26 individual defendants liable. *See South Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 782 (9th Cir.
 27 2008).” (Order at 6:5-7.) Given the reference to *South Ferry*, the Court appears to have
 28 concluded that the FAC adequately alleged scienter. The Order does not address the issue of
 whether four of the six individual defendants (Perry, Bischofberger, Carraciolo and Lee) could be
 held liable as primary violators of section 10(b) even though Plaintiffs did not allege that they
 personally made any false statements or were involved in preparing any false statements.

1 *Berry* and *Cylink* and numerous other cases, the Non-Speaking Defendants who are not alleged to
 2 have substantially participated in the preparation of any of the alleged false statements are not
 3 primary violators of section 10(b) and must be dismissed. *See also In re Intern. Rectifier Corp.*
 4 *Sec. Litig.*, No. CV07-02544-JFW (VBKx) 2008 WL 4555794, at *10–12 (C.D. Cal. May 23,
 5 2008) (dismissing Executive VP of Global Sales, VP of subsidiary company, and VP of
 6 company’s automotive products division who directed fraudulent shipment of products to meet
 7 revenue expectations because they were not alleged to have been involved in preparing
 8 company’s public statements); *Commc’ns Workers of Am. Plan for Employees’ Pensions and*
 9 *Death Benefits v. CSK Auto Corp.*, Nos. CV06-1503-PHX-DGC, CV06-1580-PHX-JWS, 2007
 10 WL 951968, at *3 (D. Ariz. Mar. 28, 2007) (dismissing President and Chief Operating Officer
 11 because there were insufficient allegations showing his involvement in preparation of alleged
 12 false statements despite his participation in conference calls where false statements were made).

13 Further, none of these individuals’ titles suggests that they would have been involved in
 14 the preparation of Gilead’s public statements. None of the Non-Speaking Defendants was the
 15 CEO or CFO; they did not sign any public statement; they are not members of the finance
 16 department; they are not in the investor relations or public relations departments; they are not on
 17 the Audit Committee or other committee that might have responsibility for reviewing and
 18 preparing public statements. In fact, Perry was in the operations department and Bischofberger
 19 and Lee were involved with research and development. (¶ 25, 26, 28.) Carraciolo is vaguely
 20 identified as a Vice President without any department attribution. (¶ 27.) There is no way the
 21 Court could conclude simply from these individuals’ titles (even if it were permissible) that they
 22 were substantially involved in the preparation of the alleged false statements.

23 **2. The PSLRA abolished the “group publishing” doctrine and the**
 24 **Plaintiffs err in attempting to rely on it.**

25 Having failed to allege specific facts showing that any of Non-Speaking Defendants
 26 substantially participated in the preparation of the alleged false statements, Plaintiffs seek to rely
 27 on the “group publishing” doctrine (also known as the “group pleading” doctrine). (*See* ¶ 30.)
 28 This doctrine is a pre-PSLRA presumption that allows company statements to be attributed

1 collectively to its officers and directors. *In re GlenFed, Inc. Sec. Litig.*, 60 F.3d 591, 593 (9th Cir.
 2 1995).

3 The group publishing doctrine is inconsistent with the heightened pleading standards of
 4 the PSLRA and should be rejected. While the Ninth Circuit has not addressed the issue, the
 5 Third, Fifth, and Seventh Circuits have all abolished the group publishing doctrine as being
 6 inconsistent with the PSLRA. *See Winer Family Trust v. Queen*, 503 F.3d 319, 334-337 (3d Cir.
 7 2007) (interpreting *Tellabs* to abolish group pleading doctrine); *Financial Acquisition Partners*
 8 *LP v. Blackwell*, 440 F.3d 278, 287 (5th Cir. 2006) (holding group pleading doctrine is
 9 inconsistent with the PSLRA); *Makor Issues & Rights, Ltd. v. Tellabs, Inc.*, 437 F.3d 588 (7th
 10 Cir. 2006), *rev'd on other grounds*, 551 U.S. 308 (2007); *see also Phillips v. Scientific-Atlanta,*
 11 *Inc.*, 374 F.3d 1015, 1018 (11th Cir. 2004) (suggesting, without resolving the question, that group
 12 pleading doctrine does not survive the PSLRA).

13 Similarly, district courts within the Ninth Circuit have rejected the group publishing
 14 doctrine as being inconsistent with the PSLRA. *In re Dot Hill Sys. Corp. Sec. Litig.*, No. 06-CV-
 15 228 JLS (WMc), 2009 WL 734296, at *12 (S.D. Cal. Mar. 18, 2009) (rejecting the group
 16 publishing doctrine and noting that weight of authority is that doctrine is inconsistent with the
 17 PSLRA); *In re Marvell Tech. Group Ltd. Sec. Litig.*, No. C-06-06286 RMW, 2008 WL 4544439,
 18 at *3-4 (N.D. Cal. Sept. 29, 2008) (holding group pleading is insufficient under the PSLRA); *In*
 19 *re Hansen Natural Corp. Sec. Litig.*, 527 F. Supp. 2d 1142, 1153-54 (C.D. Cal. 2007) (rejecting
 20 group publishing doctrine and dismissing four defendants who did not make any statements); *In*
 21 *re Amgen Inc. Sec. Litig.*, 544 F. Supp. 2d 1009, 1036 (C.D. Cal. 2008) (reviewing debate over
 22 group pleading, holding that it no longer applies and dismissing the non-speaking defendants); *In*
 23 *re Nextcard Inc. Sec. Litig.*, No. C 01-21029 JF (RS), 2006 WL 708663, at *3 (N.D. Cal. Mar. 20,
 24 2006) (holding that group publishing doctrine, which would hold corporate officers responsible
 25 for unattributed statements based on their titles and day-to-day involvement with the company, is
 26 inconsistent with particularity requirements of PSLRA).

27 Accordingly, this Court should join the three circuit courts (and the numerous district
 28 courts within the Ninth Circuit) that have addressed the issue, reject the group publishing doctrine

1 as being inconsistent with the particularity requirements of the PSLRA, and dismiss the Non-
 2 Speaking Defendants.

3 **C. Plaintiffs Fail to State a Claim for Violation of Section 20(a).**

4 Count II of the Fifth Amended Complaint alleges that the individual defendants violated
 5 section 20(a) of the Exchange Act, under which a person who controls a violator of section 10(b)
 6 is liable jointly and severally with and to the same extent as that violator. 15 U.S.C. § 78t(a). To
 7 establish “control person” liability under section 20(a), Plaintiffs must show that a primary
 8 violation of section 10(b) was committed and that each defendant directly or indirectly controlled
 9 the violator. *Paracor Fin., Inc. v. Gen. Elec. Capital Corp.*, 96 F.3d 1151, 1161 (9th Cir. 1996).

10 Plaintiffs’ failure to adequately plead a primary violation of section 10(b) requires the
 11 dismissal of this claim as to all Defendants. *Id.* Further, even assuming an adequate allegation of
 12 a primary violation of section 10(b), Plaintiffs have not pleaded facts sufficient to establish
 13 control person liability. To support a section 20(a) claim, Plaintiffs “must provide some factual
 14 support that defendants were in a position to control a primary violator;” mere boilerplate
 15 allegations of control are insufficient. *In re Intern. Rectifier*, 2008 WL 4555794, at *22; *see also*
 16 *In re Hansen*, 527 F. Supp. 2d. at 1163. Plaintiffs have provided no specific allegations regarding
 17 who had control over Gilead’s press releases and financial statements. *See Howard*, 228 F.3d at
 18 1066 (“actual authority over the preparation and presentation to the public of the financial
 19 statements is sufficient to make out a *prima facie* case”). Rather, Plaintiffs lump all the
 20 individuals together and make the boilerplate assertion that “the Individual Defendants were able
 21 to, and did, control the contents of the Company’s SEC filings.” (¶ 30.) Thus, Plaintiffs have
 22 provided no specific allegations as to any individual defendant that he controlled a primary
 23 violator. Plaintiffs’ failure is particularly glaring with regards to Defendants Perry,
 24 Bischofberger, Carraociolo, and Lee, all of whom were vice presidents at the company. There are
 25 no allegations as to the responsibilities of these individuals and there is no basis to conclude that a
 26 Vice President of Research or Vice President of Operations would have control over the
 27 individuals responsible for the Company’s public statements. *See In re Intern. Rectifier*, 2008
 28 WL 4555794, at *22 (dismissing Executive Vice President of Global Sales and Marketing

1 because his position would not establish control and plaintiffs failed to plead that he had authority
 2 over press releases and public statements).

3 Accordingly, because Plaintiffs have failed to allege a primary violation of section 10(b)
 4 and have also failed to allege specific facts demonstrating that any individual defendant
 5 controlled a primary violator, the section 20(a) claims must be dismissed.

6 **V. CONCLUSION**

7 Plaintiffs have failed to cure the deficiencies identified by this Court when it dismissed the
 8 FAC. There are still no reliable allegations of significant sales during the class period resulting
 9 from off-label marketing. Thus, the complaint should be dismissed as to all defendants. As to
 10 defendants Perry, Bischofberger, Carraciolo, and Lee, Plaintiffs have failed to allege that they
 11 made any false statements or were substantially involved in the preparation of any false
 12 statement. Hence, these Non-Speaking Defendants are not primary violators of section 10(b) and
 13 must be dismissed from the suit on this independent ground. Furthermore, the lack of a primary
 14 violation of section 10(b) and Plaintiffs' failure to allege specific facts demonstrating that any of
 15 the individual defendants controlled a primary violator require the dismissal of the section 20(a)
 16 claim as well.

17 After six tries, Plaintiffs have demonstrated that amending this complaint yet again would
 18 be futile. Defendants respectfully request that this Court dismiss the Fifth Amended Complaint
 19 with prejudice and finally let the Company and the individual defendants put this case behind
 20 them.

21 Dated: August 12, 2009

COOLEY GODWARD KRONISH LLP

23 /s/ John C. Dwyer

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